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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,033	12/22/2004	Douglas P. Nesta	P51355	6961

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EXAMINER	
DIBRINO, MARIANNE NMN	
ART UNIT	**PAPER NUMBER**
1644	
MAIL DATE	**DELIVERY MODE**
05/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,033	NESTA, DOUGLAS P.	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/26/05 & 12/22/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 1/22/04 is acknowledged and has been entered.

2. The reference "CA" crossed out in Applicant's Form 1449 filed 8/26/05 is a duplicate entry of that in Applicant's Form 1449 filed 12/22/04.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over R&D Focus Drug News (04 Oct. 1999, IDS reference) in view of US Patent No. 6,171,586 B1 (IDS reference).

R&D Focus Drug News teaches the humanized mAb C242-DM1 alone and conjugated to a toxin, and administration of the conjugate to mice and humans.

R&D Focus Drug News does not teach the antibody formulated as recited in the instant claims.

US Patent No. 6,171,586 BI discloses humanized mAbs at concentrations ranging from about 0.1 mg/ml to about 50 mg/ml in stable aqueous formulation comprising a polyol such as sucrose or trehalose in the concentration range from about I% to about 15% w/v, succinic acid buffer at about 1 mM to about 50 mM at pH range from about 4.5 to about 6.0, and administration of the said antibody formulations to humans (especially Abstract, column 2 at lines 25-29, column 6 at lines 38-67, column 7 at lines 1-3, column 2 at lines 1-43, examples 1 and 2 and claims). US Patent No. 6,171,586 B1 further discloses that the said antibody formulations are stable following freezing and thawing of the formulation and are stable at a temperature of about 2-8 degrees C for at least one year (especially column 2 at lines 25-34).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have formulated the antibody or antibody conjugated taught by R&D Focus Drug News in the formulation disclosed by US Patent No. 6,171,586 BI.

One of ordinary skill in the art at the lime the invention was made would have been motivated to do this in order to create stable aqueous formulations of the antibody taught by R&D Focus Drug News that are stable following freezing and thawing as taught by US Patent No. 6,171,586 B1 and for long term storage at about 2-8 degrees C for one year.

5. Claims 1, 2, 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over R&D Focus Drug News (04 Oct. 1999, IDS reference) in view of WO 97/04801 A1 (IDS reference).

R&D Focus Drug News teaches the humanized mAb C242-DM1 alone and conjugated to a toxin, and administration of the conjugate to mice and humans.

R&D Focus Drug News does not teach the antibody formulated as recited in the instant claims.

WO 97/04801 A1 teaches a stable aqueous formulation for subsequent lyophilization, said formulation comprising protein, including a humanized antibody, in amount from about 5 to 40 mg/ml in a pH-buffered solution at a pH from about 4-8, further comprising sucrose or trehalose in an amount from about 10-100 mM or about 10mM to about 400 mM, a buffer such as histidine or succinate at about 1 mM to about 20 mM and a surfactant . WO 97/04801 A1 teaches that after lyophilization, the lyophilized preparation may be reconstituted at very high protein concentration and is stable (especially page 3 at lines 19-28, page 8 at lines 4-38, page 14 at lines 34-39, page 15 at lines 1-21).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have formulated the antibody or antibody conjugated taught by R&D Focus Drug News in the formulation taught by WO 97/04801 A1.

One of ordinary skill in the art at the lime the invention was made would have been motivated to do this in order to create stable aqueous formulations of the antibody taught by R&D Focus Drug News that would be suitable for lyophilization and reconstitution at high protein concentration and stability as taught by WO 97/04801 A1.

With regard to the limitation of "sucrose in about 5% w/v," WO 97/04801 A1 does not teach a % w/v for the sucrose, but it does teach sucrose in the range from about 10mM to about 400 mM which range includes about 5% w/v sucrose.

6. Claims 1, 2, 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over R&D Focus Drug News (04 Oct. 1999, IDS reference) in view of EP 1516628 A1.

R&D Focus Drug News teaches the humanized mAb C242-DM1 alone and conjugated to a toxin, and administration of the conjugate to mice and humans.

R&D Focus Drug News does not teach the antibody formulated as recited in the instant claims.

EP 1516628 A1 teaches a stable aqueous formulation for subsequent lyophilization, said formulation comprising protein, including a humanized antibody, in amount from about 5 to 40 mg/ml in a pH-buffered solution at a pH from about 4-8, further comprising sucrose or trehalose in an amount from about 10-100 mM or about 10mM to about 400 mM, a buffer such as histidine or succinate at about 1 mM to about 20 mM and a surfactant . WO 97/04801 A1 teaches that after lyophilization, the lyophilized preparation may be reconstituted at very high protein concentration and is stable (especially [0056], [0039], [0042], [0027][0031], [023], [0017], [0006], [0067], [0068], [0069]).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have formulated the antibody or antibody conjugated taught by R&D Focus Drug News in the formulation taught by EP 1516628 A1.

One of ordinary skill in the art at the lime the invention was made would have been motivated to do this in order to create stable aqueous formulations of the antibody taught by R&D Focus Drug News that would be suitable for lyophilization and reconstitution at high protein concentration and stability as taught by EP 1516628 A1.

With regard to the limitation of "sucrose in about 5% w/v," EP 1516628 A1 does not teach a % w/v for the sucrose, but it does teach sucrose in the range from about 10mM to about 400 mM which range includes about 5% w/v sucrose.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Y. Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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